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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/962,094	10/31/97	BILLING-MEDEL	P 5995.US.P1

HM12/0325

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EXAMINER	
ARTHUR, L	
ART UNIT	**PAPER NUMBER**
1634	9

DATE MAILED: 03/25/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/962,094	Applicant(s) Billings-Medel et al.
	Examiner First Last	Group Art Unit 1234

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-39* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-39* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, 30, 33, 35,38,39, drawn to a method for detecting a BS106 polynucleotide, BS106 polynucleotides, vectors, kits and cells, classified in class 436, subclasses 6,320.1, 235 and Claims 536, subclass 23.5, 24,31 and 24.33.

II. Claims 17-19,21,22,25,28,29,34,36, drawn to a BS106 polypeptide, a kit containing the polypeptide, method of making the polypeptide and a method of using the polypeptide to detect an antibody, classified in class 435, subclass 7.1 and 69.1 and Class 530, subclass 350.

III. Claims 20,23,24,26,27,31,32,37, drawn to an antibody, a kit containing the antibody , a method of making the antibody and a method of using the antibody to detect a protein, classified in class 435, subclass 7.1 and Class 350, subclass 387.1 and 413.

The inventions are distinct, each from the other because:

A) The inventions of Groups I , II and III are patentably distinct because they are drawn to different compounds having different structures and different functions. The polypeptide of Group II is composed of amino acids bound in peptide bonds and which assumes a complex secondary and tertiary form. The nucleic acid of Group I is composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The polypeptide can function for the production of antibodies and in an assay for the detection of breast cancer while the nucleic acid can function as a probe or primer for the detection and amplification of the gene.

The polypeptide composition of Group II is patentably distinct from the antibody of Group III because the polypeptide has a completely different structure, i.e. amino acid sequence, secondary and tertiary structures, from the antibody and because the polypeptide and the antibody have distinct functions. Namely, the expression of the polypeptide may be associated with breast cancer and can be used to stimulate an immune response while the antibody can be used in an assay to detect or purify the polypeptide by chromatography. Consequently, the polynucleotide, the polypeptide and the antibody can be used for distinct purposes and are therefore novel and unobvious over each other.

B) Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide can be used in a materially different process than for making a polypeptide such as in a hybridization method for detection of a gene sequence or for the amplification of a particular nucleotide sequence. Furthermore, the polypeptide can be made by a materially different process such as by classical protein purification techniques, i.e. chromatography.

C) Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Group II can be used in a materially different process than for making antibodies such as for detection of antibodies or as a therapeutic composition. Furthermore, the antibodies can be used in a materially different process than for detecting the presence of the polypeptide such as in a method of making an antibody or as a secondary labeling compound in an ELISA

D) The methods of Groups II and III are patentably distinct method because they have different objective, use different reagents and have different reaction parameters. A method for detecting a polypeptide in a sample using an antibody would be expected to have different reaction parameters than a method for detecting an antibody using a polypeptide because the concentration of the polypeptide and the type of sample containing the polypeptide would be expected to be different from the concentration and sample type for the antibody. Expression of a polypeptide occurs in particular cells in response to different conditions such as the occurrence of breast cancer, for example. The antibody would not be expected to be present in a patient sample because the polypeptide is not a foreign polypeptide which is introduced into the body to trigger the production of antibodies. Therefore, the presence of antibodies would not be expected to be a reflection of breast cancer cells in an analogous manner to the presence of the polypeptide. Therefore, for these reasons, the methods are novel and unobvious over one another.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was made to Cheryl Becker on March 22, 1999, to request an oral election to the above restriction requirement, but did not result in an election being made because the attorney asked for a written copy of the restriction requirement.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa Arthur whose telephone number is (703) 308-3988. The examiner can normally be reached on Monday-Wednesday from 7:00AM to 3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Lisa B. Arthur

LISA B. ARTHUR
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

March 24, 1999